K113273

JAN 2 7 2012

510(K) SUMMARY

A. Submitter Information

DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person:	Laura Bleyendaal
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B. Date Prepared January 23, 2012

C. Device Name

Trade/Proprietary Name:	SPOTLIGHT™ PL
Common/Usual Name:	Retractor
Device Class:	Class II
FDA Product Code:	GZT- Retractor, self-retaining, for neurosurgery FSQ- Light, surgical, instrument
Regulation:	Self-retaining retractor for neurosurgery per 21 CFR § 882.4800 Surgical lamp per 21 CFR § 878.4580

D. Predicate Device Name

Trade name: DePuy Spine, Inc. SPOTLIGHT™ Access System (K062814)
Medtronic, Inc. MAST QUADRANT™ Retractor System (K043602)

V. Mueller® Cardinal Health Versa-Trac® Lumbar Retractor System (K964402)

E. Device Description

The SPOTLIGHT™ PL is a modular three blade expandable retractor, with the option of lighted and non lighted blades, which provides access to the spine for minimally invasive procedures. A fiber optic Y cable is included for use with the retractor.

The SPOTLIGHT™ PL also contains surgical instruments and cases that are considered exempt from premarket notification.

F. Intended Use

The SPOTLIGHT™ Access System and SPOTLIGHT™ PL are intended to provide the surgeon with minimally invasive surgical access to the spine by ensuring the placement/positioning of the port or retractor, down to the posterior and posterolateral bony spinal elements. These ports and retractors provide access to the spinal site which can be visualized using a microscope or loupes, and through which surgical instruments can be manipulated.

G. Summary of Similarities and Differences in Technological Characteristics

i. The proposed retractor features modular reusable blades like the predicate MAST QUADRANT™ and Versa-Trac® retractors. The proposed blade lengths are consistent with the predicate Versa-Trac® Lumbar Retractor System blade offerings.

ii. The proposed retractor may be connected to a rigid arm similar to the predicate MAST QUADRANT™ retractor and SPOTLIGHT™ Access System ports.

iii. The proposed retractor includes an integrated light source like the predicate SPOTLIGHT™ Access System ports. Specifically, lateral blades with integrated fiber optics are available for use with the proposed retractor. Non lighted lateral blades are available as well. A fiber optic Y cable is included to connect the two lateral blades with integrated fiber optics to a light cable.

iv. The proposed retractor may also accommodate a third party light source on the middle blade similar to the MAST QUADRANT™ retractor.

H. Materials

The components of the proposed retractor are manufactured from stainless steel (for the retractor handle and blades) and proprietary fiber optics in a bonding material (for the lighted blades). The Y cable is manufactured from stainless steel, rigid plastic, flexible rubber, and proprietary fiber optics.

I. Performance Data

Test System	Study Results	Conclusions
Thermal Testing	The maximum surface temperature in IEC 60601-2-18 for medical equipment applied parts was not exceeded	Pass

J. Conclusion

The substantial equivalence justification and thermal testing data demonstrate that the device is as safe and as effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Spine, Inc.
c/o Ms. Laura Bleyendaal
Regulatory Affairs Associate
325 Paramount Drive
Raynham, MA 02767

JAN 27 2012

Re: K113273
Trade/Device Name: SPOTLIGHT™ PL
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-Retaining Retractor for Neurosurgery
Regulatory Class: Class II
Product Code: GZT and FSQ
Dated: November 4, 2011
Received: November 7, 2011

Dear Ms. Bleyendaal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113273

Device Name: SPOTLIGHT™ PL

Indications For Use:
The SPOTLIGHT™ Access System and SPOTLIGHT™ PL are intended to provide the surgeon with minimally invasive surgical access to the spine by ensuring the placement/positioning of the port or retractor, down to the posterior and posterolateral bony spinal elements. These ports and retractors provide access to the spinal site which can be visualized using a microscope or loupes, and through which surgical instruments can be manipulated.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JEFFREY TOY

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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